

UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA

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SAVANNAH FLORES,

Plaintiff,

v.

MERCK & CO., INC., *et al.*,

Defendants.

Case No. 3:21-cv-00166-MMD-CLB

ORDER

**I. SUMMARY**

Plaintiff Savannah Flores sued Defendants Merck & Company, Inc. and Merck Sharp & Dohme, Corporation (collectively “Merck”) for injuries she allegedly suffered after receiving Merck’s Gardasil vaccine. (ECF No. 1 at 5.) Before the Court is Merck’s motion to dismiss (ECF No. 23 (“Motion”))<sup>1</sup> under Federal Rule of Civil Procedure 12(b)(6).<sup>2</sup> Because Flores failed to plead facially plausible claims and because some of her claims are preempted by the National Childhood Vaccine Injury Act (“Vaccine Act”), and as further explained below, the Court will grant the Motion and will grant Flores leave to amend some of her claims.

**II. BACKGROUND**

The following allegations are adapted from the Complaint unless noted otherwise. (ECF No. 1.)

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<sup>1</sup>Flores filed an opposition to the Motion (ECF No. 27), and Merck filed a reply (ECF No. 29). Flores requested an oral argument but fails to elaborate or provide any reasoning as to why such a hearing is warranted. (ECF Nos. 27, 28.) After reviewing the briefs, the Court finds that an oral argument is unnecessary and declines Flores’ request.

<sup>2</sup>The Court declines to take judicial notice of Merck’s exhibits in support of its Motion because the Court does not rely on the exhibits, and consideration of the documents is not appropriate at the motion to dismiss stage without converting the Motion to one for summary judgment under Rule 12(d). (ECF No. 24.)

1 Merck is the “designer, manufacturer, labeler, and promoter” of the Gardasil  
2 vaccine. (*Id.* at 6.) Merck represents that the Gardasil vaccine, first approved by the  
3 United States Food and Drug Administration (“FDA”) in 2006, helps protect against  
4 certain strains of the Human Papillomavirus (“HPV”) that cause HPV-related cancers,  
5 including cervical, vulvar, vaginal, and anal cancer, and also genital warts. (ECF Nos. 1  
6 at 12-13, 23 at 3-4.)

7 Flores allegedly received her first shot of Gardasil at the age of 14 and her  
8 second shot at the age of 15. (ECF No. 1 at 51.) Her mother allegedly consented to  
9 Flores receiving the vaccine because Flores’ pediatrician, Dr. Stewart Tatum, told them  
10 Gardasil was “a safe and effective vaccine for preventing cervical cancer.” (*Id.* at 52.)  
11 Flores’ mother also saw marketing and advertising by Merck that the vaccine was safe.  
12 (*Id.* at 51-52.) After receiving the vaccine, Flores began experiencing symptoms, such  
13 as fatigue, dizziness, nausea, and increased hair growth on her body. (*Id.* at 52.) Flores  
14 has subsequently been diagnosed with “postural orthostatic tachycardia syndrome  
15 (“POTS”); orthostatic intolerance (“OI”); autonomic dysfunction; hypoaldosteronism;  
16 hirsutism; and chronic migraines,” which she attributes to the vaccine. (*Id.* at 53.)

17 Flores allegedly filed a petition with the United States Court of Federal Claims to  
18 receive compensation for her vaccine-related injuries, as required by the National  
19 Vaccine Injury Compensation Program. (*Id.* at 54.) See 42 U.S.C. § 300aa–11(a)(2)(A).  
20 After judgment was rendered around April 10, 2019, Flores filed this lawsuit against  
21 Merck. (*Id.*)

22 In her Complaint, Flores asserts the following claims against Merck: (1)  
23 negligence, (2) strict liability failure to warn, (3) strict liability manufacturing defect, (4)  
24 breach of express warranty, and (5) common law fraud. (*Id.* at 55-72.) Merck now seeks  
25 dismissal of the claims. (ECF No. 23.)

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### III. LEGAL STANDARD

A court may dismiss a plaintiff's complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). A properly pleaded complaint must provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). While Rule 8 does not require detailed factual allegations, it demands more than "labels and conclusions" or a "formulaic recitation of the elements of a cause of action." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555). "Factual allegations must be enough to rise above the speculative level." *Twombly*, 550 U.S. at 555. Thus, to survive a motion to dismiss, a complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570).

In *Iqbal*, the Supreme Court of the United States clarified the two-step approach district courts are to apply when considering motions to dismiss. First, a district court must accept as true all well-pleaded factual allegations in the complaint; however, legal conclusions are not entitled to the assumption of truth. See *Iqbal*, 556 U.S. at 678. Mere recitals of the elements of a cause of action, supported only by conclusory statements, do not suffice. See *id.* Second, a district court must consider whether the factual allegations in the complaint allege a plausible claim for relief. See *id.* at 679. A claim is facially plausible when the plaintiff's complaint alleges facts that allow a court to draw a reasonable inference that the defendant is liable for the alleged misconduct. See *id.* at 678.

Where the complaint does not permit the Court to infer more than the mere possibility of misconduct, the complaint has "alleged—but it has not show[n]—that the pleader is entitled to relief." *Id.* at 679 (alteration in original) (quotation marks and citation omitted). That is insufficient. When the claims in a complaint have not crossed the line from conceivable to plausible, the complaint must be dismissed. See *Twombly*, 550 U.S. at 570. Dismissal of a complaint without leave to amend is only proper when it

1 is clear the complaint could not be saved by any amendment. *Ariz. Students' Ass'n v.*  
2 *Ariz. Bd. of Regents*, 824 F.3d 858, 871 (9th Cir. 2016); see also Fed. R. Civ. P.  
3 15(a)(2) (instructing district courts to “freely give leave” to amend).

#### 4 **IV. DISCUSSION**

5 Merck argues that the Court should dismiss all of Flores’ claims because they are  
6 either insufficiently pled, preempted and barred by the Vaccine Act, and/or barred by the  
7 learned intermediary doctrine. (ECF No. 23 at 2.) The Court agrees, but finds that some  
8 of Flores’ claims may be cured by amendment. The Court first addresses Flores’  
9 negligence, failure to warn, and breach of express warranty claims, which it finds are  
10 partially preempted by the Vaccine Act and/or barred by the learned intermediary  
11 doctrine. The Court then examines Flores’ manufacturing defect and fraud claims, which  
12 it finds are insufficiently pled. For the reasons stated below, the Court will grant Merck’s  
13 Motion.

##### 14 **A. Preemption for Negligence Claim**

15 To start, part of Flores’ negligence claim is preempted and barred by the Vaccine  
16 Act. Merck argues, in part, that dismissal is proper because Flores’ negligence is a  
17 “poorly disguised” design-defect claim, which is preempted by the Vaccine Act. (*Id.* at  
18 6.) Flores counters, in part, that none of her five claims have a design defect title, and  
19 her allegations merely “support traditional claims” for negligence. (ECF No. 27 at 8-9.)  
20 The Court agrees with Merck.

21 The Vaccine Act expressly provides that “[n]o vaccine manufacturer shall be  
22 liable in a civil action for damages arising from a vaccine-related injury or death  
23 associated with the administration of a vaccine after October 1, 1988, if the injury or  
24 death resulted from side effects that were unavoidable even though the vaccine was  
25 properly prepared and was accompanied by proper directions and warnings.” See 42  
26 U.S.C. § 300aa–22(b)(1). In interpreting this statutory text, the United States Supreme  
27 Court held that the Vaccine Act “pre-empts all design-defect claims against vaccine  
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1 manufacturers brought by plaintiffs who seek compensation for injury or death caused  
2 by vaccine side effects.” *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011).

3 Accepting Flores’ allegations as true, she appears to allege, in parts of her  
4 negligence claim, that the design of Gardasil is defective or inherently flawed, which is  
5 essentially a design defect claim. (ECF No. 1 at 23-26, 55-61.) For instance, Flores  
6 contends that Merck was negligent because it “had a duty to exercise reasonable care  
7 in the design” of Gardasil, and Merck breached its duty by failing to exercise ordinary  
8 care in the “development” of Gardasil. (*Id.* at 55-56.) She also suggests that existing  
9 ingredients in Gardasil were toxic or unsafe. (*Id.* at 57.) To the extent Flores’ negligence  
10 claim<sup>3</sup> is premised on Gardasil’s design defects, it is preempted by the Vaccine Act and  
11 barred. See 42 U.S.C. § 300aa–22(b)(1); *Bruesewitz*, 562 U.S. at 243. The Court  
12 therefore dismisses with prejudice, the part of Flores’ negligence claim that is  
13 predicated on Gardasil’s design defects.

14 Next, the remaining parts of Flores’ negligence claim do not comply with Federal  
15 Rule of Civil Procedure 8(a) because they are unclear and appear to aggregate several  
16 distinct theories of liability. Rule 8(a) requires that pleadings contain “a short and plain  
17 statement of the claim showing that the pleader is entitled to relief[.]” Rule 8(a)’s  
18 pleading requirements can be violated not only “when a pleading says too little,” but  
19 also “when a pleading says too much.” *Knapp v. Hogan*, 738 F.3d 1106, 1109 (9th Cir.  
20 2013), *cert. denied*, 574 U.S. 815 (2014); *see also McHenry v. Renne*, 84 F.3d 1172,  
21 1179-80 (9th Cir.1996) (affirming a dismissal under Rule 8, and recognizing that  
22 “[p]rolix, confusing complaints such as the ones plaintiffs filed in this case impose unfair  
23 burdens on litigants and judges”).

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25 <sup>3</sup>While the design-defect allegations are most prevalent in Flores’ negligence  
26 claim, the Court notes similar language in her failure to warn claim and other parts of  
27 the Complaint. For instance, in her failure to warn claim, Flores contends that Merck  
28 had a duty to properly “design” its vaccine to ensure that Gardasil “did not cause users  
and consumers to suffer from unreasonable and dangerous risks.” (ECF No. 1 at 62.)  
To the extent her failure to warn claim or any other claims are predicated on Gardasil’s  
design defects, those parts are dismissed with prejudice for the reasons stated above.  
The Court cautions Flores against the inclusion of design-defect allegations in future  
pleadings.

Here, Flores’ negligence claim is lengthy, difficult to follow, and replete with run-on sentences. (ECF No. 1 at 55-61.) Flores includes a superfluous number of allegations, including but not limited to, Merck’s purported failure to exercise reasonable care in the “design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and distribution of Gardasil,” flaws in Merck’s clinical trials, Merck’s failure to warn parents of Gardasil’s defects, failure to adequately test the efficacy and safety of Gardasil, concealment of information, false advertising and “disease mongering,” and failure to disclose ingredients. (*Id.*) The section’s unnecessary lengthiness and Flores’ aggregation of claims, some of which are unrelated to her specific injuries in this case, clearly ignore Rule 8(a)’s requirement of a “short and plain statement.” See *Knapp*, 738 F.3d at 1109; *McHenry*, 84 F.3d at 1179-80. The Court therefore dismisses the remaining parts of Flores’ negligence claim without prejudice, and with leave to amend.<sup>4</sup>

## **B. Preemption for Failure to Warn Claims**

The Court first addresses the partial preemption of Flores’ strict liability failure to warn claim by the Vaccine Act, and then examines the partial preemption of Flores’ breach of express warranty claim. The Court will also address the partial barring of both claims by the learned intermediary doctrine under Nevada law.

### **1. Strict Liability Failure to Warn**

Flores’ strict liability failure to warn claim is partially preempted and barred. Merck argues that the Vaccine Act and the learned intermediary doctrine foreclose “any theory of liability premised on Merck’s alleged failure to warn” Flores and her mother. (ECF No. 23 at 10.) Flores counters that Merck still “had a duty to provide accurate information in [its] advertisements” because Merck “engaged in direct-to-consumer advertising.” (ECF No. 27 at 13.) The Court agrees with Merck.

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<sup>4</sup>Although Rule 8(a) violations were most pervasive in Flores’ negligence claim, the Court notes similar issues throughout Flores’ 79-page Complaint. (ECF No. 1.) The Court cautions Flores to abide by Rule 8’s requirements in future pleadings or her claims may be subject to dismissal.

1           Flores' failure to warn claim is premised on Merck's failure to disclose Gardasil's  
 2      risks and "lack of efficacy" to Flores, Flores' mother, *and* Flores' medical providers.  
 3      (ECF No. 1 at 62-66.) First, Merck's alleged failure to warn Flores and her mother is  
 4      preempted by the Vaccine Act, which explicitly provides that "[n]o vaccine manufacturer  
 5      shall be liable in a civil action for damages arising from a vaccine-related injury or death  
 6      associated with the administration of a vaccine after October 1, 1988, solely due to the  
 7      manufacturer's failure to provide direct warnings to the injured party (or the injured  
 8      party's legal representative) . . ." See 42 U.S.C. § 300aa-22(c). The Ninth Circuit also  
 9      emphasized that the Vaccine Act "eliminat[es] [manufacturer] liability for not providing  
 10     direct warnings to a claimant," and explicitly held that the Act preempts all "failure to  
 11     warn claims arising out of a vaccine-related injury or death, not just those that could  
 12     have first been brought in the Vaccine Court." *Holmes v. Merck & Co., Inc.*, 697 F.3d  
 13     1080, 1083, 1087 (9th Cir. 2012) (emphasis added). In light of the aforementioned  
 14     statutory language and the Ninth Circuit's clear holding in *Holmes*, the Court will dismiss  
 15     with prejudice the part of Flores' claim that is premised on Merck's failure to warn Flores  
 16     and her mother.<sup>5</sup> See *id.*

17           Second, even if the Vaccine Act did not partially preempt Flores' failure to warn  
 18     claim, the claim would still be partially barred by the learned intermediary doctrine under  
 19     Nevada law. The learned intermediary doctrine traditionally immunizes drug  
 20     manufacturers from liability "to a patient taking the manufacturer's drug so long as the  
 21     manufacturer has provided the patient's doctor with all relevant safety information for  
 22     that drug" and shifts the responsibility to the patient's doctor to "convey to the patient  
 23     any information that the doctor deems relevant." *Klasch v. Walgreen Co.*, 264 P.3d  
 24     1155, 1158 (Nev. 2011) (en banc) (citation omitted).

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25           <sup>5</sup>In her response, Flores appears to argue that Merck still had a duty to warn her  
 26     and her mother because the company engaged in direct-to-consumer advertising. (ECF  
 27     No. 27 at 13.) However, the Court is unpersuaded because the express statutory  
 28     language of the Vaccine Act and prior holdings by the Ninth Circuit and the Nevada  
 Supreme Court do not support this exception under the Vaccine Act and/or Nevada's  
 learned intermediary doctrine. See 42 U.S.C. § 300aa-22(c); *Holmes*, 697 F.3d at 1083,  
 1087; *Klasch*, 264 P.3d at 1158.



1           The Nevada Supreme Court previously adopted the learned intermediary  
2 doctrine in the context of a pharmacist and customers, where it held that pharmacists do  
3 not have a “duty to warn of a prescribed medication’s generalized risks.” *Id.* at 1157-58.  
4 Since *Klasch*, judges in this district have extended the doctrine to drug and medical  
5 device manufacturers. See *Phillips v. C.R. Bard, Inc.*, Case No. 3:12-cv-00344-RCJ-  
6 WGC, 2014 WL 7177256, at \*9 (D. Nev. Dec. 16, 2014); *Flowers v. Eli Lilly & Co.*, Case  
7 No. 3:14-cv-00094-LRH-VPC, 2015 WL 12622058, at \*2-\*3 (D. Nev. July 10, 2015);  
8 *Heinrich v. Ethicon, Inc.*, 455 F. Supp. 3d 968, 974 (D. Nev. 2020). Consistent with the  
9 reasoning in *Klasch*, where “the doctor is in the best position to warn the customer of a  
10 given medication’s generalized risks,” this Court predicts that the Nevada Supreme  
11 Court would likewise extend the learned intermediary doctrine to vaccine  
12 manufacturers. See 264 P.3d at 1159. Merck therefore does not have a duty to warn  
13 Flores and her mother of the generalized risks associated with Gardasil, and this part of  
14 Flores’ claim is dismissed with prejudice.

15           Finally, Flores’ remaining allegation that Merck failed to warn her medical  
16 providers is insufficiently pled. (ECF Nos. 1 at 62-66, 27 at 13.) To prevail on a strict  
17 liability claim, the plaintiff must demonstrate “(1) the product had a defect which  
18 rendered it unreasonably dangerous, (2) the defect existed at the time the product left  
19 the manufacturer, and (3) the defect caused the plaintiff’s injury.” *Fyssakis v. Knight*  
20 *Equip. Corp.*, 826 P.2d 570, 571 (Nev. 1992) (citation omitted). Product warnings must  
21 “adequately communicate any dangers that may flow from the use or foreseeable  
22 misuse of a product.” *Yamaha Motor Co., U.S.A. v. Arnoult*, 955 P.2d 661, 665 (Nev.  
23 1998) (citation omitted). “Strict liability may be imposed even where the product is  
24 faultlessly made, if it was unreasonably dangerous to place the product in the hands of  
25 the consumer without adequate warnings concerning its safe and proper use.” *Id.*  
26 (citation omitted).

27           Here, Flores broadly alleges that Merck failed to warn “medical providers” of  
28 Gardasil’s “dangerous propensities” and true risks. (ECF Nos. 1 at 62-63, 27 at 13.) To



1 start, it is unclear from the Complaint which medical provider Merck failed to warn—  
 2 whether it was Dr. Tatum, the physician who recommended Gardasil to Flores, or  
 3 another medical professional.<sup>6</sup> (ECF No. 1 at 62-66.) Next, Flores’ allegations are  
 4 conclusory and do not yield a facially plausible claim. *See Iqbal*, 556 U.S. at 678. She  
 5 suggests that Merck knew about Gardasil’s “dangerous propensities” and its  
 6 “carcinogenic characteristics and autoimmune-inducing characteristics,” but failed to  
 7 warn medical providers. (ECF No. 1 at 63.) However, Flores fails to clarify what these  
 8 characteristics were, and which risks were and were not conveyed to Flores’ doctor,  
 9 specifically. (*Id.*) Finally, Flores’ failure to warn claim is excessively long, difficult to  
 10 follow, and fails to comply with Rule 8(a) requirements. (*Id.*) *See Knapp*, 738 F.3d at  
 11 1109; *McHenry*, 84 F.3d at 1179-80. The Court therefore dismisses without prejudice,  
 12 the part of Flores’ claim that is premised on Merck’s failure to warn her medical  
 13 providers, and grants Flores leave to amend.

## 14 **2. Breach of Express Warranty**

15 Because Flores’ breach of express warranty claim is a veiled failure to warn  
 16 claim, the Court will also dismiss it. Flores alleges that Merck’s express representations  
 17 about Gardasil “included incomplete warnings and instructions,” and Merck failed to  
 18 warn of all the risks associated with Gardasil. (ECF No. 1 at 68-71.) The core  
 19 allegations and language in Flores’ breach of warranty and failure to warn claims are  
 20 almost identical. (*Id.* at 62-71.) Because Flores’ warranty claim is a veiled failure to warn  
 21 claim, Merck’s representations and statements to Flores’ mother would be preempted  
 22 by the Vaccine Act. *See Holmes*, 697 F.3d at 1083, 1087. Even if preemption did not  
 23 apply, this part of her claim would still be barred by the learned intermediary doctrine.  
 24 *See Klasch*, 264 P.3d at 1158.

25 Notably, Flores does not deny that part of her warranty claim may be foreclosed  
 26 by the learned intermediary doctrine. (ECF No. 27 at 16.) She, instead, argues that her  
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28 <sup>6</sup>In her response, Flores alleges that Merck failed to warn her doctor, but fails to  
 clarify who this doctor was. (ECF No. 27 at 13.)

1 claim is “not predicated solely on Merck’s warranties to [her] mother” but also on  
2 Merck’s warranties to the medical community. (*Id.*) The Court therefore dismisses with  
3 prejudice the part of her breach of warranty claim that is predicated on Merck’s  
4 representations to her mother because it is barred by the Vaccine Act and the learned  
5 intermediary doctrine. See *Carter v. Ethicon, Inc.*, Case No. 2:20-cv-1232-KJD-VCF,  
6 2021 WL 1226531, at \*4 (D. Nev. Mar. 31, 2021) (granting summary judgment because  
7 the plaintiffs’ “fraud-based claims and warranty claims are simply repackaged failure-to-  
8 warn claims”).

9 Next, Flores fails to state a facially plausible claim for Merck’s alleged breach of  
10 express warranty to her medical providers. First, Flores vaguely alleges that Merck  
11 made misrepresentations to her medical providers and the medical community, but fails  
12 to specify which providers Merck made the warranties to. (ECF No. 1 at 68-71.) Such  
13 bare allegations and lack of information violate Rule 8’s notice requirements. See *Iqbal*,  
14 556 U.S. at 678.

15 Second, Flores fails to substantiate how Merck’s representations became part of  
16 the basis of the bargain—an element of breach of express warranty claims. See NRS §  
17 104.2313(1) (providing that express warranties are created by “(a) [a]ny affirmation of  
18 fact or promise made by the seller to the buyer which relates to the goods and becomes  
19 part of the basis of the bargain . . . [or] (b) [a]ny description of the goods which is made  
20 part of the basis of the bargain . . .”); see also *Radcliff v. Amiraslanov*, 381 P.3d 653  
21 (Nev. 2012). Instead, Flores makes conclusory allegations and refers to the fact that her  
22 mother would not have consented had she been adequately informed. (ECF No. 1 at  
23 70-71.) But Flores fails to provide any facts that elucidate the agreement between  
24 Merck and her doctor. (*Id.* at 68-71.) Dismissal of this part of Flores’ claim is therefore  
25 warranted because she fails to plead facts to support all elements of the claim.

26 Moreover, Nevada statutes suggest that, prior to bringing a breach of warranty  
27 claim, the plaintiff must first provide the defendant with some type of pre-suit notice. See  
28 NRS § 104.2607(3)(a) (providing that “[t]he buyer must within a reasonable time after

the buyer discovers or should have discovered any breach notify the seller of breach or be barred from any remedy”); *see also* *Banh v. Am. Honda Motor Co., Inc.*, Case No. 2:19-cv-05984-RGK-AS, 2019 WL 8683361, at \*11 (C.D. Cal. Dec. 17, 2019); *Heath v. Tristar Prods., Inc.*, Case No. 2:17-cv-2869-GMN-BNW, 2019 WL 4738004, at \*8 (D. Nev. Sept. 27, 2019). Flores has not alleged that she provided Merck with pre-suit notice, and the plain language of the statute does not provide for an exception where there is a lack of privity between the parties. (ECF Nos. 1 at 68-71, 27 at 17, 29 at 8.) See NRS § 104.2607(3)(a). The Court therefore dismisses Flores’ breach of express warranty claim, as to her medical providers, without prejudice and with leave to amend.

### C. Strict Liability Manufacturing Defect

Flores has not sufficiently pled her strict liability manufacturing defect claim. Merck argues that dismissal is proper because Flores fails to allege that the vaccine dosage she received deviated from manufacturing standards. (ECF No. 23 at 8-9.) The Court agrees with Merck.

In Nevada, the consumer-expectation test is used to determine liability for a manufacturing defect claim.<sup>7</sup> *See Ford Motor Co. v. Trejo*, 402 P.3d 649, 653 (Nev. 2017) (citations omitted). Under this test, the plaintiff must show the product “failed to perform in the manner reasonably to be expected in light of its nature and intended function and was more dangerous than would be contemplated by the ordinary user having the ordinary knowledge available in the community.” *Id.* at 652 (citing *Ginnis v. Mapes Hotel Corp.*, 470 P.2d 135, 138 (Nev. 1970)). However, “proof of an unexpected, dangerous malfunction may suffice to establish a prima facie case for the plaintiff of the existence of a product defect.” *Stackiewicz v. Nissan Motor Corp. in U.S.A.*, 686 P.2d 925, 928 (Nev. 1984).

Flores alleges that the Gardasil vaccine she received was “defective and unreasonably dangerous” because it contained undisclosed toxins like phenylmethylsulfonyl fluoride (PMSF) and HPV L1-DNA fragments, which does not

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<sup>7</sup>The Court incorporates by reference the strict liability legal standard described in Section B.1.

1 comply with governing manufacturing protocol. (ECF No. 1 at 66-67.) However, Flores  
2 also suggests in her Complaint that certain “toxins” were already present in Gardasil, as  
3 approved by the FDA. (*Id.* at 23-26.) To the extent Flores’ claim takes issue with  
4 Gardasil’s intended design or *approved* vaccine components, her claim would be  
5 preempted and barred by the Vaccine Act, as explained above. See 42 U.S.C. §  
6 300aa–22(b)(1); *Bruesewitz*, 562 U.S. at 243.

7 To the extent Flores is alleging that her Gardasil shots *deviated* from the  
8 approved or intended vaccine design, she has failed to allege a plausible claim. (ECF  
9 No. 1 at 66-68.) Flores contends that her Gardasil shots violated manufacturing  
10 specifications, but then puzzlingly states that the Gardasil products she received did not  
11 have a “substantial change in their condition as designed, manufactured, sold,  
12 distributed, labeled, and marketed by Merck.” (ECF Nos. 1 at 67, 23 at 8.) This  
13 significant contradiction does not yield a facially plausible manufacturing defect claim.  
14 See *Iqbal*, 556 U.S. at 678. Because Flores fails to allege the vaccine that she received  
15 was more dangerous than contemplated by an ordinary user, or that her specific shots  
16 deviated from Gardasil’s approved design, the Court dismisses her claim without  
17 prejudice and with leave to amend. See *Ford Motor Co.*, 402 P.3d at 653; *Stackiewicz*,  
18 686 P.2d at 928.

#### 19 **D. Fraud**

20 Finally, Flores fails to meet the heightened pleading standard for fraud claims  
21 under Rule 9(b). Merck argues, in part, that dismissal is appropriate because Flores’  
22 fraud allegations are too vague, and she fails to plead with particularity. (ECF No. 23 at  
23 15-16.) Flores counters, in part, that her allegations satisfied the elements for fraud  
24 under Nevada law and she “identif[ied] the circumstances constituting fraud so that  
25 Merck can prepare an adequate answer.” (ECF No. 27 at 18-20.) The Court agrees with  
26 Merck.

27 Rule 9(b) provides that when a party alleges fraud, the party must “state with  
28 particularity the circumstances constituting fraud.” The party must include the “the who,

1 what, when, where, and how of the misconduct charged.” *Becerra v. Dr. Pepper/Seven*  
 2 *Up, Inc.*, 945 F.3d 1225, 1228 (9th Cir. 2019) (citation omitted); *see also Depot, Inc. v.*  
 3 *Caring for Montanans, Inc.*, 915 F.3d 643, 668 (9th Cir. 2019) (noting that “the complaint  
 4 must include an account of the time, place, and specific content of the false  
 5 representations as well as the identities of the parties to the misrepresentations”) (citations and quotation marks omitted).

7 Accepting Flores’ allegations as true, she first contends that Merck “duped” her  
 8 mother into believing Gardasil was safe and effective. (ECF No. 1 at 75.) She alleges  
 9 that Merck misrepresented to her mother, through advertisements like the “One Less”  
 10 campaign, that Gardasil can prevent cancer, and only had minor risks—while failing to  
 11 disclose Gardasil’s chronic and debilitating effects. (*Id.* at 73.) However, Flores fails to  
 12 provide specific details<sup>8</sup> regarding exactly *when* her mother saw those advertisements  
 13 and was exposed to Merck’s alleged misrepresentations, as required by Rule 9(b). (*Id.*  
 14 at 72-77.) *See Becerra*, 945 F.3d at 1228; *Depot*, 915 F.3d at 668.

15 Flores also makes broader allegations that Merck engaged in other fraudulent  
 16 conduct that caused medical providers, regulators, and the general public to believe that  
 17 Gardasil was safe and effective. (ECF No. 1 at 75.) These allegations stray even further  
 18 from Rule 9(b)’s specificity requirements. Flores fails to clarify *who* these parties were,  
 19 *when* and *where* these fraudulent activities occurred, and *what* was specifically  
 20 misrepresented to these parties. (*Id.* at 75-76.) *See Becerra*, 945 F.3d at 1228; *Depot*,  
 21 915 F.3d at 668. Instead, Flores vaguely lists a series of allegations from the first 50  
 22 pages of her Complaint regarding general issues with Merck’s clinical trials, the placebo  
 23 used, and vaccine ingredients. (*Id.*) Flores therefore fails to meet the heightened

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24 <sup>8</sup>In her response, Flores seems to suggest that dismissal is improper because  
 25 she provided sufficient facts to support the elements for fraud under Nevada law. (ECF  
 26 No. 27 at 18-19.) Even if this was true, dismissal is still warranted because Flores must  
 27 follow federal procedural law when pleading her fraud claim under diversity jurisdiction.  
 28 *See Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 839 (9th Cir. 2020) (noting that  
 “[u]nder the doctrine first prescribed in *Erie* . . . federal courts exercising diversity  
 jurisdiction must follow state substantive law and federal procedural law when  
 adjudicating state law claims”) (citation omitted).

1 pleading standard under Rule 9(b), and the Court dismisses her fraud claim without  
2 prejudice and with leave to amend.<sup>9</sup>

3 **V. CONCLUSION**

4 The Court notes that the parties made several arguments and cited to several  
5 cases not discussed above. The Court has reviewed these arguments and cases and  
6 determines that they do not warrant discussion as they do not affect the outcome of the  
7 issues before the Court.

8 It is therefore ordered that Merck's motion to dismiss (ECF No. 23) is granted.

9 Flores' negligence claim, to the extent it is predicated on any design defects of  
10 the Gardasil vaccine, is dismissed with prejudice; the remainder of her negligence claim  
11 is dismissed without prejudice and with leave to amend.

12 Flores' strict liability failure to warn claim, to the extent it is predicated on Merck's  
13 failure to warn her and her mother, is dismissed with prejudice; and to the extent it is  
14 predicated on Merck's failure to warn her physician, is dismissed without prejudice and  
15 with leave to amend.

16 Flores' breach of express warranty claim, to the extent it is predicated on Merck's  
17 warranties to her mother, is dismissed with prejudice; and to the extent it is predicated  
18 on Merck's warranties to her physician, is dismissed without prejudice and with leave to  
19 amend.

20 Flores' strict liability manufacturing defect claim and fraud claim are dismissed  
21 without prejudice and with leave to amend.

22 It is further ordered that, if Flores decides to file an amended Complaint—to the  
23 extent she is able to cure the deficiencies discussed herein—she must do so within 30

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28 <sup>9</sup>As stated above, the Court notes that Flores' fraud claim is excessively lengthy.  
(ECF No. 1 at 72-77.) The Court cautions Flores to comply with Rule 8(a) requirements  
and exclude unnecessary details in future pleadings to avoid dismissal.

1 days of the date of entry of this order. Flores' failure to file an amended Complaint within  
2 30 days will result in dismissal of the remaining part of her claims with prejudice.

3 DATED THIS 16<sup>th</sup> Day of March 2022.

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6 MIRANDA M. DU  
7 CHIEF UNITED STATES DISTRICT JUDGE  
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